UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,451	08/21/2003	Joseph L. Bryant	4115-150 CIP DIV	7909

23448 7590 03/21/2007

INTELLECTUAL PROPERTY / TECHNOLOGY LAW
PO BOX 14329
RESEARCH TRIANGLE PARK, NC 27709

EXAMINER	
NOBLE, MARCIA STEPHENS	
ART UNIT	**PAPER NUMBER**
1632	

MAIL DATE	DELIVERY MODE
03/21/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	Application No. 10/645,451	Applicant(s) BRYANT ET AL.	
	Examiner Marcia S. Noble	Art Unit 1632	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 13 February 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
   b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☒ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See Continuation Sheet*. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1-11*.
   Claim(s) withdrawn from consideration: *12-21*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

Anne-Marie Falk

ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER

Continuation of 3. NOTE: The proposed amendments to the claims recite, "wherein the transgenic rate is adapted to model human HIV infection". The specification provides no literal support for this recitation. Applicant suggests that this new recitation is supported by the specification on page 5, lines 19-23. However, this reference teaches non-human transgenic models for lentiviral infection and development of diseases. Applicant also suggests that pages 19-23 support this recitation. However, pages 19-23 teach non-infectious transgenic animal models. Neither of these references provide teachings on how the claimed transgenic rat can be "adapted to model human HIV infection", therefore providing no figurative support for the breadth of this recitation. Therefore, because the amendment to the claims introduces new matter, the amendment will not be entered.

Continuation of 11. does NOT place the application in condition for allowance because:
Scope of Enablement
Claims 1-11 stands rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a transgenic rat, whose genome comprises a transgene encoding a portion of or a full length CD4 protein that binds to gp120 and CCR5 or CXCR4, if present, and mediates entry of HIV and wherein the CD4 transgene contains a PMBC specific promoter resulting in expression of the CD4 on PMBCs of the transgenic rat and wherein the transgenic rat further comprises a second transgene in its genome encoding a CCR5 or CXCR4 wherein the second transgene comprises a PMBC specific promoter resulting in the expression of CCR5 or CXCR4 on PMBCs, does not reasonably provide enablement for a transgenic rat, whose genome comprises at least one copy of a transgene encoding at least a portion of a CD4 protein sufficient for binding to gp120, wherein CD4 encoded by the transgene is expressed on PMBCs of the transgenic rat and wherein the genome further comprises a transgene encoding for at least a portion of CCR5 or a gene encoding CXCR4. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.
Applicant argues that the amendment to the claims overcome this grounds of rejection. This argument is not found persuasive because the proposed amendments are not being entered. Therefore the rejection is being maintained.

New Matter
Claims 5 stands rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.
Applicant travereses this rejection on the grounds that the recitation, "wherein the at least a portion of a CD4 protein and the at least a portion of CCR5 encoded by the transgene" has been amended and therefore, this recitation no longer constitutes as new matter. This argument is not found persuasive because the proposed amendments are not being entered. Therefore, the rejeciton is maintained.

112 2nd Paragraph
Claim 5 stands rejected under 35 U.S.C. 112, second paragraph, as being indefinite in its reciation of "the encoded transgene" and "the encoded transgene is capable of mediating entry of HIV".
Applicatn traverses this rejection on the grounds that the amendments changed the recitation to "the respective transgene". Applicant's arguments are not found persuasive because the proposed amendments to the claims are not being entered. Therefore, the rejection is maintained.

102e rejection
Claims 1-11 stand rejected under 35 U.S.C. 102(e) as being anticipated by Goldsmith et al (US Pat # 6,372,956 B1 4/16/2002; filing date 12/23/1999).

Applicant traverese this rejection on the grounds that this art does not qualify as prior art because of the claimed priority benefit to US Pat No 6,156,952. Priority to this Patent was denied because the the specification was not enabling for the breadth of the claimed invention. Because the the proposed amendments are not being entered, the scope of the invention has not changed and therefore, the priority document still does not provide enablement for the breadth of the claimed invention. Therefore, the instant patent does serve as prior art and therefore the rejection of record is maintained.

103a rejections

Claims 1-10 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Browning et al (PNAS 94:14637-14641, 1997).
Applicant traverses this rejection on the grounds that the art does not teach transgenic rat that is adapted to model human HIV infection as the amended claims require. These arguments are not found persuasive because the proposed amendment to the claims are not being entered and therefore there is still no requirement the the transgenic animal closly model human HIV infection as argued. Therefore, the rejection is maintained.

Claims 11 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Sawada et al (J Exp Med 187(9):1439-1449).
Applicant traverses this rejection on the grounds that Sawada et al can not serve as prior art because of Applicant's benefit of priority to US Pat No. 6,156,952. As stated above, the priority document does not provide enablement for the breadth of the claimed invention and therefore Applicant does not receive benefit of the priority document. Therefore, Sawada et al serves as prior art and therefore the rejection is maintained.